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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,314	10/24/2005	Anthony Rosenzweig	00786/431002	9779

21559 7590 07/28/2006

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EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/534,314	ROSENZWEIG ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,20, 21, 29, 30, 42, 45-49, 51, 54 and 55* is/are pending in the application. JE.

4a) Of the above claim(s) *15,16,20,21,30,42,45-49,51,54 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group III, drawn to a human cardiomyocyte expressing a dominant negative FADD protein, in the reply filed on 06/26/2006 is acknowledged. The traversal is on the ground(s) that the restriction of the claimed invention into Groups I-VII as not being so linked as to form a single inventive concept under PCT rule 1.31 is improper because the art that teaches the technical feature linking Groups I-VI, (i.e., Chao et al. - J Biol Chem, 2002, 277: 31639-31645) represents Applicants' own work published less than one year prior to filing of the instant application and therefore does not constitute prior art under 35 U.S.C. § 102. Accordingly, Applicants argue, all claims contain a single inventive concept under PCT Rule 1.31 and 37 C.F.R. § 1.475 and the restriction requirement should be withdrawn. This is not found persuasive because the publication by Chao et al. is by "another" (i.e., the authors of the paper are Chao, Shen, Li, and Rosenzwig that cumulatively represent another authorship as compared to Rosenzweig and Chao, the inventive entity of the instant application) and therefore clearly constitute prior art under 35 U.S.C. § 102(a). The following is a citation from MPEP:

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless —
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14, 17-19, 22-28, 31-41, 43, 44, 50, 52, 53, and 56-64 have been cancelled.

Claims 15, 16, 20, 21, 30, 42, 45, 46-49, 51, 54, and 55 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/26/2006.

Claim 29 is under examination.

Note: Change in Art Unit and SPE

The Examiner of record is now Ileana Popa, Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE and the Art Unit.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Fig. 8D, 9A, and 12C are not of sufficient quality. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The scope of claim 29, as written, encompasses a human being having a naturally occurring mutation that results in the expression of a dominant negative FADD protein. Human beings represent non-statutory subject matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seino et al. (Annals of Surgery, 2001, 234: 681-688), in view of Heinke et al. (Cardiovascular Research, 2001, 49: 127-134).

Seino et al. teach that a dominant negative FADD protein blocks Fas- and TNFR1-mediated apoptosis via FADD without affecting NF-κB activation and that

expression of this dominant negative FADD protein in the rat liver protects the animal against liver injury (p. 682, column 1, second paragraph, p.683, column 2, p. 685, column 1 bridging column 2, p. 686, column 1, second paragraph). Seino et al. teach that the dominant negative FADD could be clinically applied for inhibiting apoptosis in injured organs while preserving a beneficial immune response for protection (i.e., preserving NF-κB activation) (p. 686, column 2 bridging p.687, p. 687, columns 1 and 2). Seino et al. do not teach expressing the dominant negative FADD protein in human cardiomyocytes. Heinke et al. teach that cardiomyopathies are associated with a progressive loss of myocytes in humans via apoptosis (p. 127, column 2). Heinke et al. teach that overexpression of Fas, FAS-L, and FADD results in the increased apoptosis observed in heart failure (p. 132, column 1, second paragraph and column 2, p. 133, column 2, Concluding Remarks). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to express the dominant negative FADD protein in the failing human cardiomyocytes to inhibit their death, with a reasonable expectation of success. The motivation to do so is provided by Seino et al. who teach the dominant negative FADD protein as an effective therapeutic strategy because it efficiently inhibits cell death induced by the wild type FADD protein in the injured organs without affecting NF-κB activation, which is beneficial for the protective immune response. One of skill in the art would have been expected to have a reasonable expectation of success in making such a composition because the art teaches that such compositions can be successfully obtained. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chao et al. (J Biol Chem, August 30, 2002, 277: 31639-31645).

Chao et al. teach that the expression of a dominant negative FADD protein in rat cardiomyocytes inhibits hypoxia-induced apoptosis (Abstract, p. 31640, column 1 and 2, p. 31641, column 2). Although Chao et al. do not teach human cardiomyocytes, they do teach that manipulating the apoptotic pathway in cardiomyocytes by using a dominant negative FADD protein may lead to novel therapeutic strategies for heart diseases (p. 31645, column 1, last paragraph). It would have been obvious to one of skill in the art, at the time the invention was made to express the dominant negative FADD protein in the hypoxic human cardiomyocytes (such as cardiomyocytes from the ischemic heart) with the intent of inhibiting their death, with a reasonable expectation of success. The motivation to do so is provided by Chao et al. who teach that such an approach could be used to treat ischemic heart disease and other heart diseases. One of skill in the art would have been expected to have a reasonable expectation of success in making such a composition because the art teaches that such compositions can be successfully obtained. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

7. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa